



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 10, 2002

MEMORANDUM

SUBJECT: **Chlorpropham (CIPC) (018301).** Revised Product Chemistry and Residue Chemistry Chapter for the Tolerance Reassessment Eligibility Decision (TRED). DP Barcode No.D283516.

FROM: Danette Drew, Chemist
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THRU: Catherine Eiden, Branch Senior Scientist
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TO: Gary Mullins, Chemical Review Manager
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INTRODUCTION

SRRD has requested that HED conduct a tolerance reassessment for the plant growth regulator chlorpropham (CIPC). This memorandum is an update to the Product Chemistry and Residue Chemistry Chapter for the Tolerance Reassessment Eligibility Decision (TRED) of February 12, 2002 (D. Drew, D280212) and incorporates, where appropriate, registrant comments from the 30-day comment period for the Human Health Risk Assessment Chapter for the TRED (2/28/02). An HED Chapter of the Reregistration Eligibility Decision Document for Chlorpropham was issued 1/95. The Product and Residue Chemistry Chapters for the Chlorpropham RED were issued 7/1/94 (D188707, D. Miller). According to the Residue Chemistry Chapter for the Chlorpropham RED, the only food/feed use of chlorpropham eligible for tolerance reassessment is postharvest application to stored potatoes. The reregistration of chlorpropham is currently being supported by the Chlorpropham Task Force II represented by Aceto Agricultural Chemicals Corporation and Cerexagri. Pin Nip, Inc is also separately pursuing the reregistration of its chlorpropham end-use product (EPA Reg. No. 65726-2). This document is an update to the 7/1/94 Product and Residue Chemistry Chapters.

BACKGROUND

Chlorpropham (isopropyl *m*-chlorocarbanilate or CIPC) is a plant growth regulator used to inhibit sprout formation on stored potato. Chlorpropham is formulated as an emulsifiable concentrate (EC) or ready-to-use solution (RTU) by Aceto Agricultural Chemicals Corporation, Cerexagri, Inc. (a wholly owned subsidiary of ATOFINA Chemicals, formerly Elf Atochem), and Pin Nip, Inc., the basic producers.

The HED Metabolism Committee has determined that the residue to be included in the tolerance expression for stored potato is chlorpropham *per se*, and that the residues to be regulated in the tolerance expression for ruminant and hog commodities are chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid (4-HSA) (Memo of 4/16/93, J. Abbotts, No Barcode and Memo of 12/17/93, J. Abbotts, No Barcode). The metabolite 3-chloroaniline should be considered in the dietary (cancer) risk assessment but does not need to be included in the tolerance expression (D. Miller, 6/1/94).

The current tolerances for the raw agricultural commodities listed in 40 CFR 180.181 for residues of chlorpropham and its 1-hydroxy-2-propyl-3'-chlorocarbanilate metabolite are established at 50 ppm in or on potatoes. The tolerance for potatoes should be reduced to 30 ppm and be expressed in terms of chlorpropham *per se*.

Interim tolerances have been established for residues of chlorpropham in or on plant and animal commodities in CFR 180.319: these interim tolerances include 0.3 ppm on spinach and 0.05 ppm in milk; meat, fat, and meat byproducts of cattle, hog, horse, and sheep. The interim tolerance for spinach should be revoked. Based on the results of a ruminant feeding study, the interim tolerance for milk should be revoked and a tolerance for the combined residues of chlorpropham and 4-HSA (4-hydroxychlorpropham-O-sulfonic acid) in milk should be established at 0.30 ppm under 40 CFR 180.181. Similarly, the interim tolerances for residues of chlorpropham in meat, fat, and meat byproducts of cattle, goat, hog, horse, and sheep should be revoked. Tolerances for the combined residues of chlorpropham and 4-HSA in livestock tissues should be established under 40 CFR 180.181 for the meat of cattle, goat, horse, sheep and hog at 0.06 ppm (method limit of quantitation), at 0.06 ppm for meat byproducts, except kidney, at 0.30 for kidney, and at 0.20 ppm for fat.

CONCLUSIONS

All product chemistry data requirements have been satisfied for the Aceto 98% T (EPA Reg. No. 2749-102), Cerexagri 99% T (EPA Reg. No. 2792-67), and Pin Nip 98% T (EPA Reg. No. 65726-2), except *data are required concerning the UV/Visible absorption* (OPPTS 830.7050) of all three products. Provided that the registrants submit the product chemistry data required in the attached summary tables for the 98-99% Ts, and either certify that the suppliers of starting materials and the manufacturing processes for the chlorpropham technical products have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages, HED has no objections to the reregistration of chlorpropham with respect to product chemistry data requirements.

All residue chemistry deficiencies noted in the 7/1/94 Chemistry Chapters of the RED have been adequately addressed with the following exceptions:

-As a result of recommended changes in the tolerance expression, the Chlorpropham Task Force II has proposed a GC/NPD method for tolerance enforcement in stored potato commodities. The method has undergone successful independent laboratory validation (ILV) as well as Agency tolerance method validation (DP Barcode D213081, 3/22/95, D. Miller). Although the Agency chemists reported acceptable recoveries of chlorpropham residues in/on raw tubers, dehydrated flakes, and french fries, the registrant had been requested (DP Barcode D213081, 3/22/95, D. Miller) to submit a revised version of the proposed analytical methods incorporating significant comments made by the Analytical Chemistry Laboratory. The revised method, when received, will be forwarded to FDA for publication in Pesticide Analytical Manual (PAM) Vol. II. *Until receipt of the revised method, the requirements for analytical methodology will remain unfulfilled.*

-The registrant (Pin Nip, Inc.) Has submitted an HPLC/UV method for tolerance enforcement in stored potato commodities. *Successful radiovalidation, confirmatory method, and independent laboratory validation are required before the Agency will initiate method validation* (D283302, 6/3/02, D. Drew).

-For the determination of chlorpropham and its 4-HSA metabolite in meat and milk, separate enforcement methods (GC/MSD for chlorpropham and HPLC for 4-HSA) have been submitted by the Task Force (DP Barcode D218755, 9/27/95, D. Miller). *Successful ILVs are required before the Agency will initiate method validation. This deficiency remains outstanding.*

Sufficient data are available to reassess the tolerances associated with chlorpropham use on potatoes (see Table 5). The submitted magnitude of the residue data indicate that the established tolerance for potato may be reduced from 50 ppm to 30 ppm, provided that the following treatment rates are not exceeded :

- aerosol fog at 0.022 lb ai/1000 lbs potato in each of two applications 90 days apart followed by direct spray at 0.0104 lb ai/1000 lbs potato; or
- aerosol fog at 0.033 lbs ai/1000 lbs potato and a second aerosol fog 140 days later at 0.017 lb ai/1000 lbs potato.

Where appropriate, labels should be amended to specify a maximum seasonal rate, maximum number of applications and a minimum retreatment interval reflecting the maximum rates and minimum intervals listed above (see Table 2).

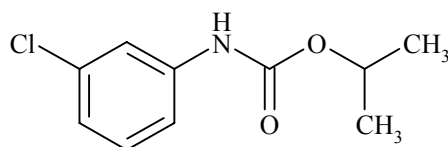
PRODUCT CHEMISTRY CONSIDERATIONS

(The product chemistry considerations were prepared by Dynamac Corp. under the supervision of HED)

The Product Chemistry Chapter of 1/7/94 has been updated below and includes products registered subsequent to that chapter: Cerexagri, Inc. 99% technical (EPA Reg. No. 2792-67) and the Pin Nip Inc. 98% technical (EPA Reg. No. 65726-2).

DESCRIPTION OF CHEMICAL

Chlorpropham (isopropyl *m*-chlorocarbanilate) is a plant growth regulator used for post-harvest treatment of potatoes. Chlorpropham is also used to prevent bud formation on ginkgo trees in Washington D.C. and to prevent bud formation and control Botrytis on Easter lilies in California and Oregon (non-food/feed uses).



Empirical Formula:	C ₁₀ H ₁₂ ClNO ₂
Molecular Weight:	213.7
CAS Registry No.:	101-21-3
PC Code:	018301

IDENTIFICATION OF ACTIVE INGREDIENT

Technical chlorpropham is an off-white to light brown solid with a melting point of 38-40°C, bulk density of 1.18 g/mL, octanol/water partition coefficient (K_{ow}) of 2.97 x 10³, and vapor pressure of 1.61-1.84 x 10⁻⁴ torr at 25°C. The solubility of chlorpropham in water at 25° C is 89 ppm. Chlorpropham is also soluble in ethyl and isopropyl alcohols, ketones, and aromatic solvents.

MANUFACTURING-USE PRODUCTS

A search of the Reference File System (REFS) conducted 9/5/01 identified four chlorpropham manufacturing-use products (MPs) under PC Code 018301: the Aceto Agricultural Chemical Corporation 98.7% and 98% technicals (Ts; EPA Reg. Nos. 2749-520 and 2749-102); Pin Nip Inc. 98% T (EPA Reg. No. 65726-2); and Cerexagri, Inc. 99% T (EPA Reg. No. 2792-67). We note that REFS identifies the Aceto 98.7% product as a technical product; however, upon examination of the CSF dated 9/15/99 and the product label (obtained from the product jacket), EPA Reg. No. 2749-520 is an end-use product which is repackaged from an EPA-registered product. REFS should be amended to list this product as an end-use product. The Aceto 98% T,

Cerexagri 99% T, and Pin Nip 98% T are the only products subject to a tolerance reassessment eligibility decision.

REGULATORY BACKGROUND

The Chlorpropham Guidance Document dated 12/87 required that all new product chemistry data be submitted in support of the reregistration of chlorpropham. Because no product chemistry data were submitted in response to the Guidance Document, the Chlorpropham Reregistration Standard Update dated 10/16/91 reiterated that all product chemistry data were required for the Aceto T/TGAI.

The unregistered TGAI for which data were summarized in the initial Chlorpropham Product Chemistry Chapter dated 7/1/94 has since been registered (EPA Reg. No. 2792-67) by Cerexagri, Inc. a wholly-owned subsidiary of ATOFINA Chemicals, Inc. (formerly Elf Atochem). The Pin Nip technical (EPA Reg. No. 65726-2) was also registered subsequent to the initial chapter.

The current status of the product chemistry data requirements for the Aceto, Cerexagri, and Pin Nip chlorpropham T/TGAIs is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

All product chemistry data requirements have been satisfied for the Aceto 98% T (EPA Reg. No. 2749-102), Cerexagri 99% T (EPA Reg. No. 2792-67), and Pin Nip 98% T (EPA Reg. No. 65726-2), except *data are required concerning the UV/Visible absorption (OPPTS 830.7050) of all three products*. Provided that the registrants submit the product chemistry data required in the attached summary tables for the 98-99% Ts, and either certify that the suppliers of starting materials and the manufacturing processes for the chlorpropham technical products have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages, HED has no objections to the reregistration of chlorpropham with respect to product chemistry data requirements.

Case No. 0271
PC Code 018301

Case Name: Chlorpropham
Registrant: Aceto Agriculture Chemicals Corporation
Product(s): 98% T (EPA Reg. No. 2749-102)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	Y	42183703 ³ , 42915101 ⁴ , CSF 5/3/00 ⁵
830.1600	Description of materials used to produce the product	Y	42183703 ³ , <u>42752201</u>
830.1620	Description of production process	Y	42183703 ³ , <u>42752201</u>
830.1670	Discussion of formation of impurities	Y	42183703 , <u>42752201</u> ³ , 42915101 ⁴
830.1700	Preliminary analysis	Y	42183702 , 42796301 ^{3,6} , 45386901 ⁷
830.1750	Certified limits	Y	42183703 , 42796301 ^{3,6} , CSF 5/3/00 ⁵
830.1800	Enforcement analytical method	Y	42796301 ^{3,6} , 45386901 ⁷
830.6302	Color	Y	<u>42737401</u> ³
830.6303	Physical state	Y	<u>42737401</u> ³
830.6304	Odor	Y	<u>42737401</u> ³
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	42183701 ³ , <u>42741101</u> ³
830.6314	Oxidation/reduction: chemical incompatibility	Y	42737401 ³ , <u>42741101</u>
830.6315	Flammability	N/A ⁸	
830.6316	Explosibility	Y	42737401 ³ , <u>42741101</u>
830.6317	Storage stability	Y	42823001 ^{3,9} , 43178101 ^{3,10}
830.6319	Miscibility	N/A ⁸	
830.6320	Corrosion characteristics	Y	42817301 ^{3,9}
830.7000	pH	Y	<u>42737401</u> ³
830.7050	UV/Visible absorption	N ¹¹	
830.7100	Viscosity	N/A ⁸	
830.7200	Melting point/melting range	Y	<u>42737401</u> ³
830.7220	Boiling point/boiling range	N/A ⁸	
830.7300	Density/relative density/bulk density	Y	<u>42737401</u> ³
830.7370	Dissociation constants in water	Y	<u>42737402</u> ³
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	<u>42737401</u> , 42754401 ³
830.7840	Water solubility: column elution method; shake flask method	Y	<u>42737401</u> , 42754301 ³
830.7950	Vapor pressure	Y	42772401 ^{3,12}

¹ Y = Yes; N = No; N/A = Not Applicable.

² **Bolded** references were reviewed under CBRS No. 9482, D174276, 7/1/92, D. McNeilly; underlined references were reviewed under CBRS No. 11816, D190890, 5/17/93, L. Cheng; and all other references were reviewed as noted.

³ RD D263703, 4/3/00, P. Horng.

⁴ CBRS No. 12555, D195145, 10/5/93, L. Cheng.

⁵ RD D266313, 5/30/00, P. Horng.

⁶ CBRS No. 11990, D192180, 6/22/93, L. Cheng.

⁷ D280213, 1/16/02, D. Drew. Preliminary analysis and enforcement analytical data requirements have already been satisfied for the Aceto 98% T/TGAI with respect to the reregistration of chlorpropham; therefore, the submitted data (MRID 45386901) will be considered supplemental. **If these data were submitted in support of an alternate manufacturing site or process, the registrant must confirm this, and additional product chemistry data may be required.**

⁸ Data are not required because the TGAI/MP is a solid at room temperature.

⁹ CBRS No. 12172, D192835, 7/21/93, L. Cheng.

¹⁰ CBRS No. 13501, D201450, 4/14/94, L. Cheng.

¹¹ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

¹² CBRS No. 11947, D191721, 6/11/93, L. Cheng.

Case No. 0271
PC Code 018301

Case Name: Chlorpropham
Registrant: Cerexagri, Incorporated
Product(s): 99% T (EPA Reg. No. 2792-67)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	Y ³	<u>42598801</u> ⁴ , CSF 6/28/00 ⁵
830.1600	Description of materials used to produce the product	Y	<u>42598801</u> ⁴
830.1620	Description of production process	Y	<u>42598801</u> ⁴
830.1670	Discussion of formation of impurities	Y	<u>42598801</u> ⁴
830.1700	Preliminary analysis	Y	42822602 ^{4,6} , 42873601 ^{4,7,8}
830.1750	Certified limits	Y ³	42822602 ⁴ , 42873601 ⁴ CSF dated 6/28/00 ⁵
830.1800	Enforcement analytical method	Y	42864501 ^{4,9}
830.6302	Color	Y	42058903 ⁴
830.6303	Physical state	Y	42058903 ⁴
830.6304	Odor	Y	42058903 ⁴
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	42855102 ^{5,10}
830.6314	Oxidation/reduction: chemical incompatibility	Y	42675602 ^{4,11}
830.6315	Flammability	N/A ¹²	
830.6316	Explosibility	Y	42807401 ^{4,13}
830.6317	Storage stability	Y	42058903 ⁴
830.6319	Miscibility	N/A ¹²	
830.6320	Corrosion characteristics	Y	42966001 ^{4,14}
830.7000	pH	Y	42058903 ⁴
830.7050	UV/Visible absorption	N ¹⁵	
830.7100	Viscosity	N/A ¹²	
830.7200	Melting point/melting range	Y	42058903 ⁴
830.7220	Boiling point/boiling range	N/A ¹²	
830.7300	Density/relative density/bulk density	Y	42058903 ⁴ , 42675601 ⁴
830.7370	Dissociation constants in water	Y	42744301 ^{5,16}
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	42855101 ^{5,10}
830.7840	Water solubility: column elution method; shake flask method	Y	42058903 ⁴ , 42822601 ⁶
830.7950	Vapor pressure	Y	42058903 ⁴ , 42864502 ^{5,9}

¹ Y = Yes; N = No; N/A = Not Applicable. The unregistered TGAI reviewed under the RED has been registered by Cerexagri, Inc. a wholly-owned subsidiary of ATOFINA Chemicals, Inc. (formerly Elf Atochem).

² **Bolded** references were reviewed under CBRS No. 8911, D170662, 7/16/92, D. McNeilly; underlined references were reviewed under CBRS No. 11132, D186321, 3/1/93, K. Dockter; and all other references were reviewed as noted.

³ The CSF dated 6/28/00 (obtained from the product jacket) must be revised to indicate the current registrant name.

⁴ RD D264619, 4/21/00, P. Horng.

⁵ RD Memorandum, D268364, 8/29/00, P. Horng.

⁶ CBRS No. 12173, D192831, 9/15/93, R. Perfetti.

⁷ CBRS No. 12400, D194316, 1/31/94, F. Toghrol.

⁸ CBRS No. 13196, D199368, 2/15/94, F. Toghrol.

⁹ CBRS No. 12401, D194319, 1/27/94, D. McNeilly.

¹⁰ CBRS No. 12330, D193854, 8/30/93, L. Cheng.

¹¹ CBRS No. 11532, D188914, 4/23/93, K. Dockter.

¹² Data are not required because the TGAI/MP is a solid at room temperature.

¹³ CBRS No. 12086, D192473, 8/31/93, K. Dockter.

¹⁴ CBRS No. 12829, D196255, 12/20/93, F. Toghrol.

¹⁵ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

¹⁶ CBRS No. 11870, D191244, 6/7/93, F. Toghrol.

Case No. 0271
PC Code 018301

Case Name: Chlorpropham
Registrant: Pin Nip, Incorporated
Product(s): 98% T (EPA Reg. No. 65726-2)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	Y	42257401 ³ , CSF 7/30/97 ³
830.1600	Description of materials used to produce the product	Y	42180902 ⁴ , 42257401 ^{3,5}
830.1620	Description of production process	Y	42180902 ^{3,4}
830.1670	Discussion of formation of impurities	Y	42180903 ^{3,4}
830.1700	Preliminary analysis	Y	42180904 ^{3,5}
830.1750	Certified limits	Y	42180904 ³ , 42180905 ⁵ , CSF 7/30/97 ³
830.1800	Enforcement analytical method	Y	42180904 ^{3,5}
830.6302	Color	Y	41013702 ⁶ , 44338301 ³
830.6303	Physical state	Y	41013702 ⁶ , 44338301 ³
830.6304	Odor	Y	41013702 ⁶ , 44338301 ³
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	41013702 ⁶ , 42741101 ⁷
830.6314	Oxidation/reduction: chemical incompatibility	Y	41013702 ⁶
830.6315	Flammability	N/A ⁸	
830.6316	Explosibility	N/A ⁹	41013702 ⁶
830.6317	Storage stability	Y	44608401 ¹⁰
830.6319	Miscibility	N/A ⁸	
830.6320	Corrosion characteristics	Y	41013702 ⁶ , 44338302 ¹⁰
830.7000	pH	Y	41013702 ⁶ , 44338301 ³
830.7050	UV/Visible absorption	N ¹¹	
830.7100	Viscosity	N/A ⁸	
830.7200	Melting point/melting range	Y	41013702 ⁶ , 42737401 ⁷
830.7220	Boiling point/boiling range	N/A ⁸	
830.7300	Density/relative density/bulk density	Y	44338301 ³ , 44372701 ¹²
830.7370	Dissociation constants in water	Y	41013702 ⁶ , 42737402 ⁷
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	41013702 ⁶ , 42754401 ⁷
830.7840	Water solubility: column elution method; shake flask method	Y	41013702 ⁶ , 42754301 ⁷
830.7950	Vapor pressure	Y	41013702 ⁶ , 42772401 ⁷

¹ Y = Yes; N = No; N/A = Not Applicable.

² All references were reviewed as noted.

³ RD D244301 and D238747, 3/16/98, P. Horng.

⁴ RD Memorandum, 1/24/95, T. Alston.

⁵ RD Memorandum, 1/31/94, T. Alston.

⁶ RD Memorandum, 3/6/95, T. Alston.

⁷ RD D264842, 4/10/00, P. Horng.

⁸ Data are not required because the TGAI/MP is a solid at room temperature.

⁹ Data are not required because the MP does not contain explosive components.

¹⁰ D28013, 1/16/02, D. Drew.

¹¹ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

¹² RD D239263, 10/31/97, S. Mathur.

RESIDUE CHEMISTRY CONSIDERATIONS

Any residue chemistry deficiencies noted in the 7/1/94 HED Residue Chemistry Chapter for chlorpropham are discussed below as well as any subsequent resolution of those deficiencies. The end- use product table (Table 1) and food/feed use pattern table (Table 2) have also been updated.

GLN 860.1200 Directions for Use

A search of the Agency's Reference Files System (REFS), conducted on 9/5/01, identified 12 chlorpropham end-use products (EPs) with postharvest uses on potatoes which are registered to Aceto Agricultural Chemicals Corporation, Cerexagri, Inc. (formerly Elf Atochem), Platte Chemical Company, Inc., Pin Nip, Inc., and Dataplex, S.A. de C.V. A list of these EPs is presented below in Table 1. There are four SLN registrations associated with chlorpropham; however, only one Special Local Need registration (SLN ME000004) has food/feed uses.

Table 1. Chlorpropham EPs with Uses on Feed/Food Crops.

EPA Reg. No.	Label Acceptance Date	Formulation Class	Product Name
Aceto Agricultural Chemicals Corp.			
2749-70	9/5/85	3 lb/gal EC	Spud Nic-3 Emulsifiable Potato Sprout Inhibitor
2749-517	5/25/95	7 lb/gal RTU	CIPC 7A Aerosol Grade Potato Sprout Inhibitor
2749-519	6/28/96	2 lb/gal EC	CIPC 2 EC Potato Sprout Inhibitor
2749-520 ¹	6/25/96	9.66 lb/gal RTU	CIPC 98A Aerosol Grade Potato Sprout Inhibitor
Cerexagri, Inc.			
2792-40	11/21/95	2 lb/gal EC	Decco 276 EC Potato Sprout Inhibitor
2792-41	12/18/90	4.3 lb/gal RTU	Pennwalt Decco 273 Aerosol Potato Sprout Inhibitor
2792-69	8/8/95	7 lb/gal RTU	Decco 270 Aerosol Potato Sprout Inhibitor
2792-70	8/8/95	9.66 lb/gal RTU	Decco 271 Aerosol Potato Sprout Inhibitor
Platte Chemical Company, Inc.			
34704-613	9/10/82	3 lb/gal EC	Sprout Nip Emulsifiable Concentrate Potato Sprout Inhibitor
34704-614	6/23/86	7 lb/gal RTU	Sprout Nip 7A Aerosol Grade Potato Sprout Inhibitor
Pin Nip, Inc.			
65726-3	10/7/97	9.709 lb/gal RTU	Pin Nip™ 98.6% Chlorpropham Aerosol Grade Potato Sprout Inhibitor
Dataplex, S.A. de C.V.			
72790-1	11/9/99	2 lb/gal EC	Pin Nip 2 EC Emulsifiable Concentrate Potato Sprout Inhibitor

¹ Including SLN ME000004.

A comprehensive summary of the registered use patterns of chlorpropham, based on these product labels, is presented in Table 2. According to Table 2, the only registered food/feed use of chlorpropham is for postharvest applications on potatoes prior to storage. Postharvest applications may be made either as an aqueous spray (using EC formulations) or as an aerosol (using RTU formulations). A tabular summary of the residue chemistry science assessments for the tolerance reassessment of chlorpropham is presented in Appendix A. The conclusions listed in Appendix A regarding the tolerance reassessment eligibility are based on the use patterns registered by the basic producers, Pin Nip, Inc., Aceto Agricultural Chemicals Corporation and Cerexagri, Inc. When end-use product DCIs are developed, RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producers labels.

Table 2. Food/Feed Use Patterns Subject To Tolerance Reassessment for Chlorpropham (PC Code No. 018301).

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single “Standard” ¹ Application Rate (ai)	Maximum Seasonal Application Rate (ai)	Maximum Number of Applications	Retreatment Interval	Use Limitations ¹
Potato						
Aqueous spray Postharvest Ground equipment	2 lb/gal EC [2792-40] [2749-519] [72790-1] 3 lb/gal EC [2749-70] [34704-613]	0.0104 lb/1000 lb potato	NS (Not specified)	NS	NS	Application is made as an aqueous spray to potato moving along a conveyor belt. Potato must be cured (allowing at least two weeks for cuts and bruises to heal) and washed prior to application. Application in the field or to seed potatoes is prohibited. Label should be amended to limit use to only one application. If potatoes have been previously treated by aerosol fogger, a minimum 5 day retreatment interval is required before treating with the EC formulation.
Aerosol application Postharvest Aerosol generator with forced air recirculation	4.3 lb/gal RTU [2792-41]	0.044 lb/1000 lb potato	NS	NS	NS	Application at the maximum application rate is to be made to potatoes which will be stored for long periods. The storage area must be kept closed during treatment and for 48 hours following treatment. Application in the field or to seed potatoes is prohibited. Cancellation Pending.
	7 lb/gal RTU [34704-614]	0.017 lb/1000 lb potato	NS	NS	NS	A maximum application rate is not specified. Number of applications and retreatment interval are not specified. Label should be amended to specify a minimum retreatment interval of 3 months (90 days). A maximum seasonal rate should be specified. A maximum of two treatments should be specified. ³
	7 lb/gal RTU [2749-517]	0.017 lb/1000 lb potato	NS (0.025 lb/1000 lb potato implied) ²	NS	NS	The storage area must be kept closed during treatment and for 4 hours following treatment or until fog settles. Application in the field or to seed potatoes is prohibited. The highest recommended rate listed is “145%” of the “standard” rate. A retreatment interval is not specified. Label should be amended to specify a minimum retreatment interval of 3 months (90 days). A maximum of two treatments should be specified. ³

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single “Standard” ¹ Application Rate (ai)	Maximum Seasonal Application Rate (ai)	Maximum Number of Applications	Retreatment Interval	Use Limitations ¹
	7 lb/gal RTU [2792-69]	0.017 lb/1000 lb potato	NS (0.025 lb/1000 lb potato implied) ²	NS	NS	<p>The storage area must be kept closed during treatment and for 4 hours following treatment or until fog settles. Application in the field or to seed potatoes is prohibited.</p> <p>The highest recommended rate listed is “145%” of the “standard” rate. A retreatment interval is not specified.</p> <p>Label should be amended to specify a minimum retreatment interval of 3 months (90 days). A maximum of two treatments should be specified.³</p>

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single “Standard” ¹ Application Rate (ai)	Maximum Seasonal Application Rate (ai)	Maximum Number of Applications	Retreatment Interval	Use Limitations ¹
Potato (continued)						
Aerosol application Postharvest Aerosol generator with forced air recirculation	9.66 lb/gal RTU [2749-520] [2792-70]	0.017 lb/1000 lb potato	NS (0.028 lb/1000 lb potato implied) ²	NS	NS	The highest recommended rate listed is “165%” of the “standard” rate. A retreatment interval is not specified. Label should be amended to specify a minimum retreatment interval of 3 months (90 days). A maximum of two treatments should be specified. ³
	9.709 lb/gal RTU [65726-3]	0.017 lb/1000 lb potato	NS (0.028 lb/1000 lb potato implied) ²	NS	NS	The highest recommended rate listed is “165%” of the “standard” rate. A retreatment interval is not specified. Label should be amended to specify a minimum retreatment interval of 3 months (90 days). A maximum of two treatments should be specified. ³
	9.66 lb/gal RTU [ME000004]	0.025 lb/1000 lb potato	NS (0.041 lb/1000 lb potato implied) ²	NS	NS	The highest recommended rate listed is “165%” of the “standard” rate. A retreatment interval is not specified. Label should be amended to specify a minimum retreatment interval of 3 months (90 days). A maximum of two treatments should be specified. ³

Note: Forced air recirculation through the pile must be used at the following rates: (i) 0.005 cubic feet per minute (CFM) per cwt (EPA Reg. No. 2749-517); (ii) 0.5 CFM per bushel of potatoes (EPA Reg. No. 2792-41); (iii) rate illegible on the label (EPA Reg. No. 2749-520).

For low volume application, use forced air recirculation through the pile at rates up to 5.0 CFM per ton of potatoes. For other applications, use the lowest forced air recirculation available for the applicator (EPA Reg Nos. 2749-520, 2792-70, 65726-3, and ME000004).

¹ See example below of the sliding scale table appearing on RTU labels where the “standard” application rate, or 100% treatment, is 0.017 lb/1000 lb potato (i.e. 1 lb ai/600 cwt).

TIME MONTHS	Storage Temperature				
	40°F	45°F	50°F	55°F	60°F
1	80%	90%	100%	110%	120%
2	85%	95%	105%	115%	125%
3	90%	100%	110%	120%	130%
4	95%	105%	115%	125%	135%
5	100%	110%	120%	130%	140%
6	105%	115%	125%	135%	145%
7	110%	120%	130%	140%	150%
8	115%	125%	135%	145%	155%
9	120%	130%	140%	150%	160%
10	125%	135%	145%	155%	165%

² The implied maximum rate is 165% of the standard rate, calculated to be 0.028 lb/1000 lb potato when standard rate is 0.017 lb/1000 lb potato or 0.041 lb/1000lb when standard rate is 0.025 lb/1000lb (or 145% of standard rate, calculated to be 0.025 lb/1000 lb potato).

³ RTU product labels state that “if potatoes are held in storage longer than originally anticipated, the potatoes may be retreated”. Although the label language implies two treatments not to exceed 165% (or 145%) of the standard rate, the total number of treatments or maximum seasonal rate, is not clearly stated. The labels should clearly state a maximum of two treatments not to exceed a total rate of 165% (or 145%) of the standard rate. Also, a retreatment interval is not specified. The label should specify a minimum retreatment interval of 3 months (90 days) to reflect the minimum retreatment interval used in the residue field trials.

GLN 860.1300 Nature of the Residue-Plants and Livestock

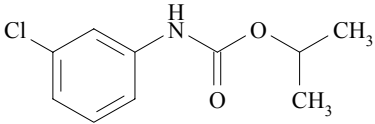
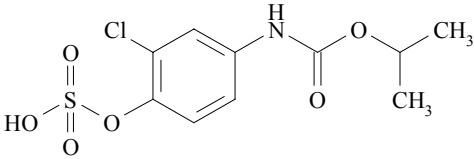
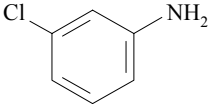
Plants

The qualitative nature of the residue in stored potato treated postharvest is adequately understood. The parent chlorpropham was found to be the major residue, representing 96% of the total radioactive residues (TRR), in potato stored for 52 weeks following treatment with [C¹⁴]chlorpropham at 2.4x the maximum registered rate. Although this indicates that little metabolism of chlorpropham occurs in stored potato, some metabolites of chlorpropham were detected (each at <1.3% of TRR), indicating that chlorpropham may metabolize through hydroxylation of the aniline ring or the isopropyl side chain, with subsequent conjugation with carbohydrates or amino acids. Decarbanilation may also occur, forming 3-chloroaniline. The regulated metabolite (1-hydroxy-2-propyl-3-chlorocarbanilate) was not detected, but an oligosaccharide conjugate of this metabolite was detected at 0.03% TRR. The 3-chloroaniline metabolite and its glucose conjugate were also identified at a combined level of 0.58% TRR.

The HED Metabolism Committee has determined that the metabolite 1-hydroxy-2-propyl-3-chlorocarbanilate does not need to be included in the tolerance expression for potato (J. Abbotts, 4/16/93). The Committee also judged that the tolerance expression in potatoes should *not* include the 3-chloroaniline compound, but that the dietary risk assessment for cancer should include this

metabolite (RED document, D. Miller, 6/1/94). This cancer dietary risk assessment should be performed using anticipated residues of 3-chloroaniline along with the q_1^* associated with 4-chloroaniline. The Committee recognized that this latter assumption may overestimate the risk associated with 3-chloroaniline, but believed that no reliable information exists at this time to refute this assumption. The chemical structures of chlorpropham and 3-chloroaniline are presented in Figure A.

Figure A

Structure Metabolite: Chemical Name	Structure Metabolite: Chemical Name
 <p>Chlorpropham: isopropyl <i>m</i>-chlorocarbanilate</p>	 <p>4-Hydroxychlorpropham-O-sulfonic acid</p>
 <p>3-Chloroaniline</p>	

Livestock

The qualitative nature of the residue in poultry is adequately understood for the purposes of the limited use of chlorpropham. Potato is not a significant poultry feed item and there are no tolerances for chlorpropham residues in poultry tissue and eggs. The qualitative nature of the residue in ruminants is adequately understood. The HED Metabolism Committee has determined that the residues to be regulated in animal commodities are chlorpropham and the metabolite 4-hydroxychlorpropham-O-sulfonic acid (J. Abbotts, 12/17/93). The Committee has judged that although 3-chloroaniline should *not* be included in the tolerance expression, the dietary risk assessment (cancer) should include the 3-chloroaniline metabolite.

The metabolism of chlorpropham in ruminants and poultry is proposed to proceed through oxidation to 4-hydroxychlorpropham or degradation to 3-chloroaniline. The hydroxychlorpropham is then further metabolized to 4-hydroxychlorpropham-O-sulfonic acid or 4-hydroxychlorpropham-O-glucuronide and the aniline is further metabolized to 3-chloro-4-hydroxyaniline-O-sulfonic acid.

GLN 860.1340 Residue Analytical Method

The PAM Vol. II lists several methods for the enforcement of chlorpropham tolerances, as currently expressed, for plant commodities and milk. The PAM Vol. I method for chlorinated pesticides is listed as Method I, and an IR method is listed as Method II. The limit of detection for Method II is 1 ppm. Methods A, B, and D are spectrophotometric methods involving conversion of chlorpropham to 3-chloroaniline; PAM notes that IPC, monuron, diuron, linuron, and any other compound forming a volatile aniline on hydrolysis will also be determined in these procedures. Method C is a GC method with electron capture detection and involves conversion of chlorpropham to bromochloroaniline. Method E is a TLC method and Method F is similar to Method II.

As a result of recommended changes in the tolerance expression, the Chlorpropham Task Force II has proposed a GC/NPD method for tolerance enforcement in stored potato commodities. The method has undergone successful ILV as well as Agency tolerance method validation (DP Barcode D213081, 3/22/95, D. Miller). Although the Agency chemists reported acceptable recoveries of chlorpropham residues in/on raw tubers, dehydrated flakes, and french fries, the registrant had been requested (DP Barcode D213081, 3/22/95, D. Miller) to submit a revised version of the proposed analytical methods incorporating significant comments made by EPA's Analytical Chemistry Branch (ACB). The revised method, when received, will be forwarded to FDA for publication in PAM Vol. II. *Until receipt of the revised method, the requirements for analytical methodology will remain unfulfilled.*

Pin Nip, Inc. has submitted an HPLC/UV method for tolerance enforcement in stored potato commodities. *Successful radiovalidation, confirmatory method, and independent laboratory validation are required before the Agency will initiate method validation* (D283302, 6/3/02, D. Drew).

For the determination of chlorpropham and its 4-HSA metabolite in meat and milk, separate enforcement methods (GC/MSD for chlorpropham and HPLC for 4-HSA) have been submitted by the Task Force (DP Barcode D218755, 9/27/95, D. Miller). *Successful ILVs are required before the Agency will initiate method validation. This deficiency remains outstanding.*

GLN 860.1360 Multiresidue Method

The FDA PESTDATA database dated 8/93 (PAM Vol. I, Appendix II) indicates that chlorpropham is completely recovered (>80%) using FDA multiresidue method protocols D (Section 232.4) and E (Section 212.1/232.1, nonfatty matrices and Section 211.1/232.1, fatty matrices).

GLN 860.1380 Storage Stability

All data requirements pertaining to chlorpropham storage stability *per se* have been evaluated and deemed adequate. Storage stability studies support the storage intervals used in the potato field trials and ruminant feeding studies. Residues of chlorpropham *per se* are stable during frozen storage at -4°C in potato and wet potato peel for 13 months, in potato chips for 8 months, in potato granules for 9 months, and in processed dry peels for 12 months (D. Miller, CBRS No. 13088).

Residues of chlorpropham were found to be stable under frozen storage in milk for 4 months, in muscle for 2 months, and in liver for 1 month. Residues of 4-HSA were found to be stable under frozen conditions in milk and muscle for 4 months, and in liver for 2 months.

GLN 860.1500 Magnitude of the Residue in Plants

All data requirements pertaining to the magnitude of chlorpropham *per se* residue in stored potato have been evaluated and deemed adequate. The submitted data indicate that the established tolerance for potato may be reduced from 50 ppm to 30 ppm, provided that the following treatment rates are not exceeded (Note: where appropriate, labels should be amended to specify a maximum seasonal rate, maximum number of applications and a minimum retreatment interval reflecting the maximum rates and minimum intervals below) :

- aerosol fog at 0.022 lb ai/1000 lbs potato in each of two applications 90 days apart followed by direct spray at 0.0104 lb ai/1000 lbs potato; or
- aerosol fog at 0.033 lbs ai/1000 lbs potato and a second aerosol fog 140 days later at 0.017 lb ai/1000 lbs potato.

Three magnitude of the residue studies were submitted by the Chlorpropham Task Force. Approximately 140,000 lbs. of potatoes were stored in each of 5 bin/fumigation chambers (12 ft by 20 ft by 27 ft high). Bin 1 held untreated control samples. Each bin was fitted with 2 sampling pipes. Each pipe had 3 sampling ports at 1, 8, and 15 feet above the bin floor air ducts. In one study, which represented residues on potatoes intended for processing into frozen or dehydrated products (MRID 42653901), bins 2 and 3 were treated twice by aerosol fog (0.022 lb ai/1000 lb potato on days 1 and 92; Maximum application rate of 0.044 lb ai/1000 lb potatoes). Samples were collected from the top, middle, and bottom sampling ports at days 0, 5, 91, 96, 140, and 215. Chlorpropham residues on whole potatoes ranged from 1.24 ppm to 24.5 ppm.

In another study (MRID 42653601; fresh harvest potatoes), samples in bins 2 and 3 were treated twice by aerosol fog (0.022 lb ai/1000 lb potato on days 1 and 92) and/or direct spray (at 0.010 lb ai/1000lb potato) on the day of sampling (maximum rate of 0.054 lb ai/1000 lb). Samples were collected from the top, middle, and bottom sampling ports at days 0, 5, 91, 96, 140, and 215 where fog treatment occurred on days 1 and 92. Chlorpropham residues on whole potatoes ranged from 2.73 ppm to 12.7 ppm.

A third study (MRID 42653801) was performed on potatoes intended for processing into potato chips. Bins 4 and 5 were treated twice by aerosol fog at two different rates (.033 lb ai/1000 lb potatoes on day 1 followed by 0.017 lb ai/1000 lb potatoes on day 141; Maximum rate of 0.050 lb ai/1000 lb). Samples were collected from the top, middle, and bottom sampling ports at days 0, 5, 91, 96, 140, , 145 and 215. Residues of chlorpropham ranged from 2.98 ppm to 24 ppm.

Magnitude of the residue data were submitted by Pin Nip, Inc.(MRID 42566801). Potatoes stored in a cellar (350 ft long by 40 ft wide, with a total capacity of 5 million lb of potatoes) were treated by aerosol fog at 0.017 lb ai/1000 lb potatoes. Potato samples were collected at six different sites from three different

levels of potato storage. Samples were collected from the top of the pile at about one-third and two-thirds the total length of the pile. Flags were placed at these two sites so all sample collections at these sites were at the same location. Samples from the other sites were obtained by cutting holes through the side wall of the air plenum. Samples were taken from a level 1 ft above the cellar floor and at 7 ft, midway between the floor at the top of the potato pile. 31 potatoes were taken from each of six collection sites at each time point, for a total of 186 potatoes for each time point. Samples were taken immediately before fumigation (0 hr), and at 2 h, 15 days, 30 days, 60 days, 90 days, and 106 days after fumigation. Residues of chlorpropham on whole potatoes ranged from 0.54 ppm to 11.4 ppm.

Residue data for the metabolite 3-chloroaniline on potatoes and processed potato commodities have also been submitted with the aforementioned magnitude of the residue studies and will be used to determine the anticipated residues of 3-chloroaniline for use in the dietary risk assessment.

GLN 860.1520 Processed Food/Feed

The registrant submitted adequate potato processing studies. Residues of chlorpropham *per se* did not concentrate in potato granules/ flakes or chips. The maximum expected residue in potato, wet peel, would be 36 ppm based on the Highest Average Field Trial (HAFT) whole potato residue (12 ppm) and the average concentration factor (3x) from a commercial-scale processed potato waste study. A tolerance for residues of chlorpropham *per se* on potato, wet peel should be established at 40 ppm.

GLN 860.1480 Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

According to the 7/94 Chemistry chapter, a ruminant feeding study remained outstanding. The Chlorpropham Task Force II submitted data depicting the magnitude of chlorpropham and 4-HSA in milk and edible tissues from lactating dairy cows as well as supporting storage stability data. The submitted dairy cattle feeding study is adequate and may be used to fulfill the residue chemistry requirements under OPPTS GLN 860.1480 (D222987, 7/9/99, D. Drew) and for tolerance reassessment.

The anticipated residues of 3-chloroaniline in milk and meat commodities for use in the cancer dietary risk assessment will be determined from the ruminant metabolism study results.

A poultry feeding study is not required as potatoes are not a significant poultry feed item. No tolerances are required for residues of chlorpropham in poultry tissue and eggs based on the current registered uses of chlorpropham on potatoes.

LIVESTOCK DIETARY BURDEN

Processed potato waste and potato culls are the only feed commodities with registered chlorpropham uses. The Maximum Theoretical Dietary Burden (MTDB) for beef and dairy cattle is 110 ppm. The MTDB for hog is 15 ppm. Calculations of MTDBs are presented in the tables below.

Table 3a: Maximum Theoretical Dietary Burden of Chlorpropham for **Beef and Dairy Cattle**.

Feed	Reassessed tolerance, ppm	Beef and Dairy Cattle		
		% of Diet ¹	% Dry Matter ¹	MTDB ² , ppm
Processed Potato Waste (wet peel)	40	40	15	110

Table 3b: Maximum Theoretical Dietary Burden of Chlorpropham for **Hog**

Feed	Reassessed RAC Tolerance, ppm	Hog	
		% of Diet ¹	MTDB ² , ppm
Culls	30	50	15

¹ As per Table 1 of OPPTS GLN 860.1000. ² MTDB= tolerance (ppm)x % of diet÷ % dry matter

Milk

In the ruminant feeding study, dairy cattle were orally administered chlorpropham at levels of 290 ppm (2.6x the MTDB cattle), 870 ppm (7.9x), and 2900 ppm (26x) for 28 consecutive days. Maximum combined residue levels of chlorpropham and its metabolite, 4-HSA, in milk plateaued on days 24, 7, and 14 of the 290 ppm, 870 ppm and 2900 pm feeding level studies, respectively. The combined residues of chlorpropham and 4-HSA are calculated to be 0.25 ppm in milk. Based on the results of tolerance reassessment for potatoes, this feeding study and the calculated MTDB, the interim tolerance for milk (40 CFR 180.319) should be revoked and a tolerance for the combined residues of chlorpropham and 4-HSA in milk should be established at 0.30 ppm under 40 CFR 180.181.

Ruminant and Hog Tissue

In the ruminant feeding study, dairy cattle were orally administered chlorpropham at levels of 290 ppm (2.6x the MTDB for cattle and 19x MTDB for hog), 870 ppm (7.9x for cattle, 58x for hog), and 2900 ppm (26x for cattle and 190x for hog) for 28 consecutive days. Combined residues of chlorpropham and 4-HSA found in livestock tissues at the 290 ppm feeding level are presented in the table below. Based on the results of the feeding study and the calculated MTDBs, the interim tolerances (40 CFR 180.319) for residues of chlorpropham in meat, fat, and meat byproducts of cattle, goat, hog, horse, and sheep should be revoked. Tolerances for the combined residues of chlorpropham and 4-HSA in livestock tissues should be established under 40 CFR 180.181 for the meat of cattle, goat, horse, sheep and hog at 0.06 ppm (method limit of quantitation) , at 0.06 ppm for meat byproducts, except kidney, at 0.30 for kidney, and at

0.20 ppm for fat.

Table 4. Combined CIPC and 4-HSA Residues in Livestock Tissue (290ppm feeding level)

Tissue	Residue at 290 ppm (2.6x for Beef; 19x for Hog) [ppm]
Muscle	0.06
Kidney	0.31
Liver	0.065
Fat	0.17

GLN 860.1850,1900 Confined/Field Rotational Crops

Rotational crop studies are not required to support use of chlorpropham on stored potato.

TOLERANCE REASSESSMENT

The HED Metabolism Committee has determined that the residue to be included in the tolerance expression for stored potato is chlorpropham *per se*, and that the residues to be regulated in the tolerance expression for ruminant and hog commodities are chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid (4-HSA) (Memo of 4/16/93, J. Abbotts, No Barcode and Memo of 12/17/93, J. Abbotts, No Barcode). The metabolite 3-chloroaniline should be considered in the dietary (cancer) risk assessment but does not need to be included in the tolerance expression (D. Miller, 6/1/94).

The current tolerances for the raw agricultural commodities listed in 40 CFR 180.181 for residues of chlorpropham (CIPC) and its 1-hydroxy-2-propyl-3'-chlorocarbanilate metabolite are established at 50 ppm in or on potatoes. The tolerance for potatoes should be reduced to 30 ppm (based on the maximum field trial residue of 24 ppm) and be expressed in terms of chlorpropham *per se*.

Interim tolerances have been established for residues of chlorpropham in or on plant and animal commodities in 40 CFR 180.319: these interim tolerances include 0.3 ppm on spinach and 0.05 ppm in milk; meat, fat, and meat byproducts of cattle, hog, horse, and sheep. The interim tolerance for spinach should be revoked as there are no registered uses of chlorpropham on spinach. Based on the results of a ruminant feeding study, and tolerance reassessment, the interim tolerance for milk should be revoked and a tolerance for the combined residues of chlorpropham and 4-HSA in milk should be established at 0.3 ppm under 40 CFR 180.181. Similarly, the interim tolerances for residues of chlorpropham in meat, fat, and meat byproducts of cattle, goat, hog, horse, and sheep should be revoked. Tolerances for the combined residues of chlorpropham and 4-HSA in livestock tissues should be established under 40 CFR 180.181 for the meat of cattle, goat, horse, sheep and hog at 0.06 ppm (method limit of quantitation), at 0.06 ppm for meat byproducts, except kidney, at 0.30 for kidney, and at 0.20 ppm for fat.

No feed/food additive tolerances have been established. The registrant submitted adequate potato processing studies. Residues of chlorpropham *per se* did not concentrate in potato granules/ flakes or chips. The maximum expected residue in potato, wet peel, would be 36 ppm based on the HAFT whole potato residue (12 ppm) and the average concentration factor (3x) from a commercial-scale processed potato waste study. A tolerance for residues of chlorpropham *per se* on potato, wet peel should be established at 40 ppm.

Table 5. Tolerance Reassessment Summary for Chlorpropham			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Tolerances listed under 40 CFR §180.181			
Potatoes (POST-H)	50	30	<i>Potato</i>
Tolerances listed under 40 CFR §180.319 (interim tolerances)			
Cattle, fat	0.05	Revoke	Establish reassessed tolerance under 180.181 (see below)
Cattle, mbyp	0.05	Revoke	Establish reassessed tolerance under 180.181
Cattle, meat	0.05	Revoke	Establish reassessed tolerance under 180.181
Goats, fat	0.05	Revoke	Establish reassessed tolerance under 180.181
Goats, mbyp	0.05	Revoke	Establish reassessed tolerance under 180.181
Goats, meat	0.05	Revoke	Establish reassessed tolerance under 180.181
Hogs, fat	0.05	Revoke	Establish reassessed tolerance under 180.181
Hogs, mbyp	0.05	Revoke	Establish reassessed tolerance under 180.181
Hogs, meat	0.05	Revoke	Establish reassessed tolerance under 180.181 (see bottom of table)
Horses, fat	0.05	Revoke	Establish reassessed tolerance under 180.181
Horses, mbyp	0.05	Revoke	Establish reassessed tolerance under 180.181
Horses, meat	0.05	Revoke	Establish reassessed tolerance under 180.181
Milk	0.05	Revoke	Establish reassessed tolerance under 180.181 (see bottom of table)
Sheep, fat	0.05	Revoke	Establish reassessed tolerance under 180.181
Sheep, mbyp	0.05	Revoke	Establish reassessed tolerance under 180.181

Table 5. Tolerance Reassessment Summary for Chlorpropham			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Sheep, meat	0.05	Revoke	Establish reassessed tolerance under 180.181
Spinach	0.3	Revoke	No registered uses
Tolerances to be proposed under 40 CFR §180.181			
Cattle, meat	None	0.06	
Cattle, fat	None	0.20	
Cattle, kidney	None	0.30	
Cattle, meat byproducts, except kidney	None	0.06	
Goat, meat	None	0.06	
Goat, fat	None	0.20	
Goat, kidney	None	0.30	
Goat, meat byproducts, except kidney	None	0.06	
Hog, meat	None	0.06	
Hog, fat	None	0.20	
hog, kidney		0.30	
Hog, meat byproducts, except kidney	None	0.06	
Horse, meat	None	0.06	
Horse, fat	None	0.20	
Horse, kidney	None	0.30	
Horse, meat byproducts, except kidney	None	0.06	
Milk	None	0.30	
Sheep, meat	None	0.06	
Sheep, fat	None	0.20	
Sheep, kidney	None	0.30	
Sheep, meat byproducts, except kidney	None	0.06	
potato, wet peel	None	40	

DIETARY EXPOSURE ASSESSMENT

Chronic and acute dietary assessments will be performed for residues of chlorpropham on potatoes and for residues of chlorpropham and 4-HSA in milk and livestock tissues. Anticipated residues will be determined using crop field trial studies, livestock feeding studies and monitoring data.

A dietary assessment for potential cancer risk will also be performed for residues of 3-chloroaniline on potatoes and livestock commodities as a result of the post- harvest treatment of potatoes with chlorpropham. Residue data for the metabolite 3-chloroaniline on potatoes and processed potato commodities have been submitted and will be used to determine the anticipated residues of 3-chloroaniline for use in the dietary risk assessment. The anticipated residues of 3-chloroaniline in milk and meat commodities for use in the cancer dietary risk assessment will be determined from the ruminant metabolism study results. Anticipated residues and the dietary assessment results will be detailed in a subsequent document.

AGENCY MEMORANDA (PRODUCT CHEMISTRY)

Date	DP Barcode	CB No.	From	To	MRID Nos.	Subject
7/1/92	D174276	9482	D. McNeilly	V. Eagle and R. Taylor	42183702 42183703	Chlorpropham; Product Chemistry
7/16/92	D170662	8911	D. McNeilly	V. Eagle and R. Taylor	42058903	Chlorpropham; Product Chemistry
3/1/93	D186321	11132	K. Dockter	W. Waldrop/V. Eagle	42598801	Reregistration of Chlorpropham [CIPC; isopropyl N-(3-chlorophenyl)carbamate]. Elf Atochem Decco [EPA Company #2792] Product Chemistry Considerations.
4/23/93	D188914	11532	K. Dockter	W. Waldrop and V. Eagle	42675601 42675602	Chlorpropham Reregistration. Elf Atochem Decco 02/17/93 Response [63-7 and 63-14 Data for "CIPC Tech"] to CBRS 07/16/92 Review #8911.
5/17/93	D190890	11816	L. Cheng	V. Eagle	42737401 42737402 42741101 42752201	Chlorpropham. Case No. 0271. Aceto's Submission on Product Chemistry (EPA Reg. No. 2749-102).
6/7/93	D191244	11870	F. Toghrol	L. Rossi/W. Waldrop	42744301	Chlorpropham Reregistration: List A Chemical (Chemical No. 018301; Case No. 0271). Elf Atochem North America, Inc.: Response to the Chlorpropham Product Chemistry Data Requirements Regarding Dissociation Constant (GLN 63-10).
6/11/93	D191721	11947	L. Cheng	V. Eagle	42772401	Chlorpropham. Case No. 0271. Aceto's Submission of §63-9 (Vapor Pressure).
6/22/93	D192180	11990	L. Cheng	V. Eagle	42796301	Chlorpropham. Case No. 0271. Aceto's Submission on Product Chemistry (EPA Reg. No. 2749-102).
7/21/93	D192835	12172	L. Cheng	V. Eagle	42817301 42823001	Chlorpropham. Case No. 0271. Aceto's Submission on Product Chemistry (EPA Reg. No. 2749-102).
8/30/93	D193854	12330	L. Cheng	V. Eagle	42855101 42855102	Chlorpropham. Case No. 0271. Elf Atochem (Registrant No. 2792) Submission on Product Chemistry.

Date	DP Barcode	CB No.	From	To	MRID Nos.	Subject
8/31/93	D192473	12086	K. Dockter	V. Eagle	42807401	Chlorpropham Reregistration. Elf Atochem Decco 6/08/93 Response [63-16 Data].
9/15/93	D192831	12173	R. Perfetti	L. Rossi and A. Rathman	42822601 42822602	Response to the Chlorpropham Reregistration Standard: Product Chemistry.
10/5/93	D195145	12555	L. Cheng	V. Eagle	42915101	Chlorpropham. Case No. 0271. Updated Product Chemistry (61-1 & 61-3) Submitted by Aceto (EPA Reg. No. 2749-102).
12/20/93	D196255	12829	F. Toghrol	L. Rossi/W. Waldrop	42966001	Chlorpropham Reregistration: List A Chemical No. 018301; Case No. 0271. Elf Atochem North America, Inc.: Response to the Chlorpropham Product Chemistry Data Requirements Regarding Corrosion Characteristics (GLN 63-20).
1/27/94	D194319	12401	D. McNeilly	V. Eagle and T. Stone	42864501 42864502	Chlorpropham Product Chemistry: Elf Atochem North America, Inc. (Hodogaya Chemical Co. Formulation).
1/31/94	D194316	12400	F. Toghrol	L. Rossi and W. Waldrop	42873601	Chlorpropham Reregistration: List A Chemical (Chemical No. 018301; Case No. 0271). Elf Atochem North America, Inc. Amendment to the Preliminary Analysis (GLN No. 62-1) of Chlorpropham 99% T.
1/31/94	None	RD Memo	T. Alston	C. Giles-Parker	42257401 42180904 42180905	Product Chemistry Review; EPA File Symbol 65726-E.
2/15/94	D199368	13196	F. Toghrol	L. Rossi/W. Waldrop	None	Chlorpropham Reregistration: List A Chemical (Chemical No. 018301; Case No. 0271). Amendment to a 1/31/94 CBRS Memorandum (CBRS No. 12400; DP Barcode: D194316). Issues Relating to Test Substance and Source of Active Ingredient.
4/14/94	D201450	13501	L. Cheng	V. Eagle-Kunst	43178101	Chlorpropham. Case No. 0271. Aceto Submission on Product Chemistry (EPA Reg. No. 2749-102).
1/24/95	None	RD Memo	T. Alston	C. Giles-Parker	42180902 42180903	Product Chemistry Review; EPA File Symbol 65726-E.

Date	DP Barcode	CB No.	From	To	MRID Nos.	Subject
3/6/95	None	RD Memo	T. Alston	C. Giles-Parker	41013702	Submission of Series 63 Data for 65726-E.
10/31/97	D239263	RD Memo	S. Mathur	C. Giles-Parker	44372701	Product Chemistry Review of TGAI; Reg./ File Symbol No. 65726-2; Product Name: Pin Nip Technical Chlorpropham; Company: Pin Nip, Inc.
3/16/98	D244301 D238747	RD Memo	P. Horng	J. Holms	42180902 42180903 42180904 42257401 44338301	Product Chemistry Review of Technical Product; Reg./File Symbol No.: 65726-2; Product Name: Pin Nip Technical Chlorpropham; Company Name: Pin Nip, Inc.; Action Code: 675, 8-Months Response to Data Call-In.
4/3/00	D263703	RD Memo	P. Horng	V. Eagle-Kunst	42183703 42737401 42737402 42741101 42752201 42754301 42754401 42772401 42796301 42823001 42915101	Product Chemistry Review of Technical Product; Case No. 010674; Reg./File Symbol No.: 2749-102; Product Name: Chloro IPC Technical; Company Name: Aceto Agricultural Chemicals Corporation; Action Code: 674 8-Month Response to Product Specific Data Call-In.
4/10/00	D264842	RD Memo	P. Horng	V. Eagle-Kunst	42737401 42737402 42741101 42754301 42754401 42772401	Product Chemistry Review of Technical Product; Reg./File Symbol No.: 65726-2; Product Name: Pin Nip Technical Chlorpropham; Company Name: Pin Nip, Inc.; Action Code: 675, 8-Months Response to Data Call-In.
4/21/00	D264619	RD Memo	P. Horng	V. Eagle-Kunst	42598801 42873601 42864501 42822602 42058903 42675601 42675602 42807401 42966001	Product Chemistry Review of Technical Product; Case No. 040862; Reg./File Symbol No.: 2792-67; Product Name: CIPC Technical; Company Name: Elf Atochem North America, Inc.; Action Code: 674, 8-Month Response to product Specific Data Call-In.

Date	DP Barcode	CB No.	From	To	MRID Nos.	Subject
5/30/00	D266313	RD Memo	P. Horng	V. Eagle-Kunst	None	Product Chemistry Review of Technical Product; Case No. 010674; Reg./File Symbol No.: 2749-102; Product Name: Chloro IPC Technical; Company Name: Aceto Agricultural Chemicals Corporation; Action Code: 674 8-Month Response to Data Call-In.
8/29/00	D268364	RD Memo	P. Horng	V. Eagle-Kunst	42744301 42855101 42855102 42864502	Product Chemistry Review of Technical Product; Case No. 040862; Reg./File Symbol No.: 2792-67; Product Name: CIPC Technical; Company Name: Elf Atochem North America, Inc.; Action Code: 674 8-Month Response to product Specific Data Call-In.
1/16/02	D280213	None	D. Drew	G. Mullins	44338302 44608401	Product Chemistry Review; Storage Stability and Corrosion Characteristics Data for the Pin Nip 98% T (EPA Reg. No. 65726-2). Reviewed within this document (Product Chemistry Data Requirements for Chlorpropham 98% and 99% Technical. D280213)
1/16/02	D280213	None	D. Drew	G. Mullins	45386901	Product Chemistry Review; Supplemental Preliminary Analysis Data and Enforcement Analytical Methods for Aceto Technical Grade Chlorpropham. Reviewed within this document (Product Chemistry Data Requirements for Chlorpropham 98% and 99% Technical. D280213)

AGENCY MEMORANDA (RESIDUE CHEMISTRY)

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham. Reregistration Case No. 0271. Issues to be Presented at the 3/16/93 Meeting of the HED Metabolism Committee.
From: J. Abbotts, CBRS, HED
To: HED Metabolism Committee
Dated: 3/10/93
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Results of the HED Metabolism Committee Meeting Held on 3/22/93: Chlorpropham Metabolism in Potatoes.
From: J. Abbotts, CBRS, HED
To: HED Metabolism Committee
Dated: 3/31/93
MRID(s): None

CBRS No.: 11008
DP Barcode: D185464
Subject: Chlorpropham. Registrant Pin Nip, Inc. Response to the Reregistration Standard: Magnitude of the Residue in Postharvest Potatoes and Potato Processed Commodities.
From: J. Abbotts, CBRS, HED
To: V. Eagle, SRRD
Dated: 4/16/93
MRID: 42566801

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham. Results of the HED Metabolism Committee Meeting Held on 3/22/93: Chlorpropham Metabolism in Potatoes.
From: J. Abbotts, CBRS, HED
To: V. Eagle, SRRD
Dated: 4/16/93
MRID(s): None

CB No.: 11846
DP Barcode: D191079
Subject: Chlorpropham. SLN 24(c) for Use on Overwintered Spinach in the State of Delaware. SLN No. DE-91-0001.
From: M. Flood, CBTS, HED
To: C. Giles-Parker/J. Stone, RD
Dated: 5/24/93

MRID(s): None

CBRS No(s).: 11217, 11422, and 11428
DP Barcodes: D186971, D188291, and D188292
Subject: Chlorpropham. Chlorpropham Task Force Response to the Reregistration Standard: Analytical Method, Magnitude of the Residue in Postharvest Potatoes, Potato Processed Commodities, and Storage Stability.
From: J. Abbotts, CBRS, HED
To: V. Eagle, SRRD
Dated: 6/21/93
MRID(s): 42610301, 42653401, 42653601, 42653701, 42653801, 42653901, 42660101, and 42660201

CBRS No.: 11948
DP Barcode: D191727
Subject: Chlorpropham Reregistration. Independent Laboratory Validation of an Analytical Method.
From: J. Abbotts, CBRS, HED
To: V. Eagle, SRRD
Dated: 7/8/93
MRID: 42778901

CBRS No.: 12273
DP Barcode: D193416
Subject: Chlorpropham Reregistration. Registrant Pin Nip, Inc. Submission of Supplemental Data: Magnitude of the Residue in Postharvest Potatoes and Potato Processed Commodities.
From: J. Abbotts, CBRS, HED
To: V. Eagle, SRRD
Dated: 8/11/93
MRID(s): None

CBRS No.: 12452
DP Barcode: D194640
Subject: Chlorpropham Reregistration. Chlorpropham Task Force Submission of Supplemental Data: Nature of the Residue in Animals.
From: J. Abbotts, CBRS, HED
To: V. Eagle, SRRD
Dated: 10/8/93
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham. Reregistration Case No. 0271. Issues to be Presented at the 11/5/93 Meeting of the HED Metabolism Committee.
From: J. Abbotts, CBRS, HED
To: HED Metabolism Committee
Dated: 11/5/93
MRID(s): None

CBRS No.: 12695
DP Barcode: D195985
Subject: Chlorpropham Reregistration. Chlorpropham Task Force Submission of Additional Data on Storage Stability.
From: J. Abbotts, CBRS, HED
To: V. Eagle, SRRD
Dated: 12/9/93
MRID: 42958301

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham Reregistration. Conclusions of the HED Metabolism Committee.
From: J. Abbotts, CBRS, HED
To: F. Chow, HED
Dated: 12/17/93
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham Reregistration. Conclusions of the HED Metabolism Committee.
From: J. Abbotts, CBRS, HED
To: W. Waldrop/V. Eagle, SRRD
Dated: 12/17/93
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham. Metabolism Committee Decision Re: Regulation of 3-CA Metabolite.
From: D. Miller, CBRS, HED
To: Metabolism Committee
Dated: 3/30/94
MRID(s): None

CBRS No.: 12232
DP Barcode: D199308
Subject: Response to Chlorpropham Task Force's January 8 1994 Request for Additional Information and Submission of Supplemental Data
From: D. Miller, CBRS, HED
To: V. Eagle, SRRD
Dated: 5/18/94
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham. Determination of Anticipated Residues of 3-Chloroaniline Metabolite in Poultry, Beef, and Milk Commodities for Use in DRES Analysis and in the Chlorpropham RED Document.
From: D. Miller, CBRS, HED
To: CBRS Files
Dated: 6/24/94
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham. Outcome of 5/19/94 Meeting of HED Metabolism Committee.
From: D. Miller, CBRS, HED
To: HED Metabolism Committee
Dated: 6/1/94
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham. Outcome of 6/9/94 Meeting of HED Metabolism Committee Meeting.
From: D. Miller, CBRS, HED
To: HED Metabolism Committee
Dated: --
MRID(s): None

CBRS No.: 13088
DP Barcode: D198109
Subject: Chlorpropham. Storage Stability on Potatoes (whole, dehydrated granules, peels, wet peels, and dry peels).
From: D. Miller, CBRS, HED
To: Venus Eagle, SRRD
Dated: --
MRID(s): 430536-01

CBRS No.: 13673
DP Barcode: D203092
Subject: Chlorpropham. Response to Pin Nip's May 5, 1994 Request for Additional Data.
From: D. Miller, CBRS, HED
To: Venus Eagle, SRRD
Dated: 5/8/94
MRID(s): None

CBRS No.: 13438
DP Barcode: D200887
Subject: Chlorpropham. ILV of Analytical Methodology in Potatoes.
From: D. Miller, CBRS, HED
To: Venus Eagle, SRRD
Dated: 6/8/94
MRID(s): 43160101

CBRS No.: 14404
DP Barcode: D207718
Subject: Chlorpropham. Response to ER Butt's August 11, 1994 Request for Information Regarding Bridging Requirements between Pin Nip Field Trials and Chlorpropham Task Force Field Trials.
From: D. Miller, CBRS, HED
To: Margery Exton, SRRD
Dated: 10/12/94
MRID(s): None

CBRS No.: 14403
DP Barcode: D207719
Subject: Chlorpropham .Response to August 2, 1994 Task Force Inquiry Regarding ILV of Analytical Methodology in Potatoes.
From: D. Miller, CBRS, HED
To: Margery Exton, SRRD
Dated: 10/12/94
MRID(s): None

CBRS No.: 15122
DP Barcode: D213081
Subject: Chlorpropham .Results of Tolerance Method Validation (TMV) on Potatoes and Processed Potato Commodities.
From: D. Miller, CBRS, HED
To: Venus Eagle, SRRD
Dated: 3/22/95
MRID(s): None

CBRS No.: None
DP Barcode: D217441
Subject: Chlorpropham(CIPC)
From: D. Miller, CBRS, HED
To: Margery Exton, SRRD
Dated: 7/19/95
MRID(s): None

CBRS No.: None
DP Barcode: None
Subject: Chlorpropham: Calculation of Potential Concentration in Processed Potato Waste.
From: D. Miller, CBRS, HED
To: Lois Rossi, Paula Deschamp
Dated: 8/3/95
MRID(s): None

CBRS No.: 16107
DP Barcode: D218755
Subject: Chlorpropham: Enforcement Analytical Method for Meat and Milk Commodities.
From: D. Miller, CBRS, HED
To: Margery Exton, SRRD
Dated: 9/27/95
MRID(s): None

CBRS No.: None
DP Barcode: D216255
Subject: Chlorpropham: Amended Use.
From: R.W. Cook, HED
To: D. McCall, HED
Dated: 7/19/96
MRID(s): None

CBRS No.: 17893
DP Barcode: D234821
Subject: Chlorpropham: Review of Protocol for Potato Processing Study.
From: D. Miller, HED
To: P. Deschamp, HED
Dated: 4/29/97
MRID(s): None

CBRS No.: 17893
DP Barcode: D239919
Subject: Chlorpropham: Request by PIN-NIP for Waiver of Enforcement Analytical Method for 3-Chloroaniline Metabolite in Potatoes.
From: D. Miller, HED
To: S. Jennings, SRRD
Dated: 10/29/97
MRID(s): None

DP Barcode: D240103
Subject: Chlorpropham: Addendum to the Chemistry Chapter of the RED; Analytical Method Requirements [HPLC/UV Method for Data Collection].
From: D. Drew, HED
To: P. Moe, SRRD
Dated: 7/1/99
MRID(s): 44397101

DP Barcode: D210640
Subject: Chlorpropham: Addendum to the Chemistry Chapter of the RED; Analytical Method Requirements [GC/NPD Method Modifications for Tolerance Enforcement of Stored Potato Commodities] (860.1340) and Magnitude of the Residue on Processed Potato Waste (860.1520).
From: D. Drew, HED
To: P. Moe, SRRD
Dated: 7/9/99
MRID(s): 43442701 and 44534501

DP Barcode: D222987
Subject: Chlorpropham: Addendum to the Chemistry Chapter of the RED; Magnitude of the Residue on Meat and Milk (Ruminant) (860.1480), Storage Stability on Meat and Milk (860.1380).
From: D. Drew, HED
To: P. Moe, SRRD
Dated: 7/9/99
MRID(s): 43884501 and 43989901

DP Barcode: D260114
Subject: Chlorpropham: Magnitude of the Residue on Potato Peels and Pulp.
From: D. Drew, HED
To: G. Mullins, SRRD
Dated: 12/17/01
MRID(s): 44736001

DP Barcode: D281664
Subject: Chlorpropham: Response to Registrant's Letter dated March 13, 2002 Regarding Agency Review of Residue Study Reports (44736001, 45426101).
From: D. Drew, HED
To: G. Mullins, SRRD
Dated: 5/6/02
MRID(s): no MRID

DP Barcode: D283302
Subject: Analytical Method of the Plant-Analysis of Chlorpropham and 3-Chloroaniline in Potato Peels, Pulp, Chips, and Granules.
From: D. Drew, HED
To: G. Mullins, SRRD
Dated: 6/3/02
MRID(s): 44397101

MASTER RECORD IDENTIFICATION NUMBERS (RESIDUE CHEMISTRY)

00035896 Wiedmann, J.L.; Pensyl, J. (1975) Proposed Regulatory Method for CIPC Residue (CIPC + Metabolite III): BR 19718. Method dated May 2, 1975. (Unpublished study received May 8, 1975 under 4F1429; submitted by PPG Industries, Inc., Barberton, Ohio; CDL: 093811-D)

00037029 Ware, G.W.; Brakel, W.J. (1963) Excretion of 3-C1-aniline and Isopropyl-N-(3-Chlorophenyl) carbamate (CIPC) in the milk and urine of dairy cows fed CIPC. *Journal of Dairy Science* XLVI(2): 120-123. (Also in unpublished submission received on unknown date under 4F1429; submitted by Pittsburgh Plate Glass Co., Morristown, N.J.; CDL:093807-P)

00045294 PPG Industries, Incorporated (1969) General Analytical Method for Determining CIPC Residues in Crops Designated in the Summary Table as Being Analyzed by MF (Ext.). (Unpublished study received Dec 31, 1970 under 1F1119; CDL:093430-D)

00045295 PPG Industries, Incorporated (1968) General Analytical Method for Determining CIPC Residues in Crops Designated in the Summary Table as Being Analyzed by the MF (TCH-Dist) Method. (Unpublished study received Dec 31, 1970 under 1F1119; CDL:093430-E)

00054669 Ware, G.W.; Brakel, W.J. (1963) Excretion of 3-Cl-aniline and Isopropyl-N-(3-chlorophenyl) carbamate (CIPC) in the milk and urine of dairy cows fed CIPC. *Journal of Dairy Science* 46:120-123. (Also in unpublished submission received Aug 26, 1977 under 4581-EX-30; submitted by Pennwalt Corp., Philadelphia, Pa.; CDL: 231831-L)

00054672 Dave, B. (1977) Residue Data of CIPC on Potatoes. (Unpublished study received Aug 26, 1977 under 4581-EX-30; submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:231831-T)

00083155 Gard, L.N. (1959) Determination of isopropyl N-(3-chlorophenyl) carbamate residues in potatoes treated for sprout inhibition. *Journal of Agricultural and Food Chemistry* 7(5):339-341. (Also in unpublished submission received Dec 1, 1959 under PP0234; submitted by Columbia-Southern Chemical Corp., Pittsburgh, Pa.; CDL:090262-G)

00114695 Fredenburg, R. (1960) Letter sent to E. Plant dated Nov 8, 1960: [Emulsifiable sprout nip: Chloro-IPC]. (Unpublished study received Feb 14, 1961 under 748-182; submitted by PPG Industries, Inc., Barberton, OH; CDL:024269-B)

00114700 Kennedy, G.; Jenkins, D. (1970) Report to PPG Industries, Inc.: Distribution of CIPC in Milk and Tissues of a Lactating Cow: IBT No. J8629A. (Unpublished study received on unknown date under 1F1119; prepared by Industrial Bio-Test Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, OH; CDL:090892-I)

00114701 Kennedy, G. (1970) Report to PPG Industries, Inc.: Tissue and Egg Residue Study of CIPC in White Leghorn Chickens: IBT No. J8630A. (Unpublished study received on unknown date under 1F1119; prepared by Industrial Bio-Test Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, OH; CDL:090892-J)

00114710 Pittsburgh Plate Glass (1967) [Study: CIPC Residue on Selected Crops]. (Compilation; unpublished study received Aug 23, 1967 under 8F0690; CDL:091198-A)

00114715 PPG Industries, Inc. (1972) Petition of PPG Industries, Inc. Pursuant to Section 408 (d)(1) of the Federal Food, Drug and Cosmetic Act with Respect to the Pesticide Chemical Chlorpropham. (Compilation; unpublished study received Jun 1, 1972 under 2F1276; CDL:092107-A)

00114718 Columbia-Southern Chemical Corp. (1960) [Analyses for Residues of CIPC and Other Chemicals in Potatoes]. (Compilation; unpublished study received on unknown date under PP0234; CDL: 092511-A)

00114739 PPG Industries, Inc. (1974) [Analyses for Residues of CIPC Chemicals in Various Products]. (Compilation; unpublished study received on unknown date under 4F1429; CDL:098173-A)

00114741 Columbia Southern Chemical Corp. (1960) [Analyses for Residues of CIPC Chemicals in Potatoes]. (Compilation; unpublished study received on unknown date under PP0234; CDL:098745-A)

00114747 PPG Industries, Inc. (1961) [Analyses for Residues of CIPC in Potatoes]. (Compilation; unpublished study received Mar 17, 1961 under unknown admin. no.; CDL:120933-A)

00114750 Food Machinery and Chemical Corp. (1956) Sprout Control in Irish Potatoes. (Unpublished study received on unknown date under unknown admin. no.; CDL:120940-A)

00114751 Gard, L. (1957?) Determination of ... (CIPC) Residues in Potatoes Treated for Sprout Inhibition. (Unpublished study received Nov 24, 1958 under unknown admin. no.; submitted by PPG Industries, Inc., Barberton, OH; CDL:120941-A)

00114777 Agchem (1978) [Analyses for Residues of CIPC in Potatoes]. (Compilation; unpublished study received Aug 14, 1978 under 4581-EX- 30; CDL:234638-A)

00114785 Agchem (1978) Residue Data of CIPC on Potatoes. (Compilation; unpublished study received Nov 21, 1978 under 4581-338; CDL: 235995-G)

00114795 PPG Industries, Inc. (1979) Summary of 1978-1979 Tests Using Decco Brand CIPC-AR under EPA Permit #4581-EUP-30. (Compilation; unpublished study received Jul 18, 1979 under 4581-EX-30; CDL: 238857-A)

00115388 PPG Industries, Inc. (1967) [CIPC: Residues in Milk and Other Subjects]. (Compilation; unpublished study received on unknown date under 1F1120; CDL:090894-A)

05016141 Ebing, W. (1972) Routine methode zur Duennschichtchromatographischen Identifizierung der Pestizidruckstaende aus den Klassen der Triazine, Carbamate, Harnstoffe und Uracile_ [Routine method for identification of pesticide residues of triazine, carbamate, urea, and uracil type compounds by thin-layer chromatography_] Journal of Chromatography 65(3):533-545.

42085601 Kim-Kang, H. (1991) Metabolism of Carbon fourteen Chlorpropham in Stored Potatoes: Nature of the Residue in Potatoes: Lab Project Number: XBL 89070: RPT0066. Unpublished study prepared by XenoBiotic Laboratories, Inc. 167 p.

42112201 Wu, D. (1991) Metabolism of Carbon 14-Chlorpropham in Lactating Goats: Metabolite Analysis and Quantitation in Milk and Tissues: Final Report: Lab Project Number: XBL 90055: RPT0061. Unpublished study prepared by XenoBiotic Laboratories, Inc. 231 p.

42123101 Moller, G. (1991) Analytical Method for Magnitude of Residues in Stored Potatoes from Postharvest Treatments of Chlorpropham: Final Report: Lab Project Number: 91CIPC01. Unpublished study prepared by Univ. of Idaho Analytical Lab, Holm Research Ctr. 87 p.

42130401 Wu, D. (1991) Metabolism of Carbon 14-Chlorpropham in Laying Hens: Metabolite Analysis and Quantitation in Eggs and Tissues: Lab Project Number: XBL 90053: RPT0073. Unpublished study prepared XenoBiotic Labs, Inc. 228 p.

42566801 Wulf, L. (1992) Final Report: Chlorpropham and 3-Chloroaniline Residue Study on Potatoes, Potato Skins, Potato Chips and Potato Granules After Post-Harvest Fumigation: Lab Project Number: 92-001. Unpublished study prepared by Hibbs Analytical Laboratories, Inc. 51 p.

42610301 Kleinkopf, G.; Thomson, C. (1992) In-life Phase Study: Magnitude of Residues in Stored Potatoes from Postharvest Treatments of Chlorpropham: Lab Project Number: 92CIPC02. Unpublished study prepared by University of Idaho. 151 p.

42653401 Walker, G.; Goodrick, B.; Haws, R.; et al. (1993) Analytical Method for Magnitude of Residues in Stored Potatoes from Postharvest Treatments of Chlorpropham: An Addendum: Lab Project Number: 92CIPC01. Unpublished study prepared by University of Idaho. 323 p.

42653601 Goodrick, B.; Haws, R.; Walker, G.; et al. (1993) Magnitude of the Residues of Chlorpropham and Major Metabolites in or on Stored Potatoes Intended for the Fresh Market: Lab Project Number: 92CIPC04. Unpublished study prepared by University of Idaho. 193 p.

42653701 Swanson, B.; Younce, F.; Englar, J.; et al. (1993) Processing of Stored Potatoes Treated Postharvest with Chlorpropham to Determine Magnitude of Residues in Processed Potato Fractions: Lab Project Number: 92CIPC03. Unpublished study prepared by Washington State Univ. 76 p.

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42653901 Goodrick, B.; Haws, R.; Walker, G.; et al. (1993) Magnitude of the Residues of Chlorpropham and Major Metabolites in or on Stored Potatoes Intended for Processing into Frozen or Dehydrated Products: Lab Project Number: 92CIPC05. Unpublished study prepared by University of Idaho. 181 p.

42660101 Haws, R.; Goodrick, B.; Walker, G.; et al. (1993) Determination of Storage Stability of Field-Incurred Residues of Chlorpropham and Metabolites of Concern in or on Fresh, Stored and Processed Potatoes: Lab Project Number: 92CIPC08. Unpublished study prepared by University of Idaho. 81 p.

42660201 Haws, R.; Goodrick, B.; Walker, G.; et al. (1993) Magnitude of the Residues of Chlorpropham and Major Metabolites in or on Processed Potato Products and Peels: Lab Project Number: 92CIPC07. Unpublished study prepared by University of Idaho. 425 p.

42778901 Boggess, K. (1993) Validation of a Method for the Determination of Chlorpropham (CIPC) and Other Target Analytes from Potato Matrices: Lab Project Number: 3304-F. Unpublished study prepared by Midwest Research Institute. 60 p.

42958301 Haws, R.; Goodrick, B.; Walker, G.; et al. (1993) Addendum 1 to Report 92CIPC08: Determination of Storage Stability of Field-Incurred Residues of Chlorpropham and Metabolites of Concern in or on Fresh, Stored and Processed Potatoes: Lab Project Number: 92CIPC08. Unpublished study prepared by Univ. of Idaho Analytical Lab. 91 p.

43053601 Goodrick, B.; Haws, R.; Moller, G. (1993) Determination of Storage Stability of Fortified Residues of Chlorpropham and Metabolites of Concern in/on Fresh, Stored, and Processed Potatoes: Lab Project Number: 93CIPC02. Unpublished study prepared by University of Idaho Analytical Lab. 273 p.

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Appendix A: Residue Chemistry Science Assessment for Chlorpropham

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
860.1200: Directions for Use	N/A = Not Applicable		(see Table 2)
860.1300: Plant Metabolism	N/A	No	42085601 ²
860.1300: Animal Metabolism	N/A	No ³	00114700, 00114701, 00114739, 42112201 ^{2,4} , 42130401 ²
860.1340: Residue Analytical Methods	N/A	Yes ⁵	00035896, 00045294, 00045295, 00114710, 00114715, 00114718, 00114739, 00114741, 00114751, 00114785, 00115388, 05016141, 42123101 ² , 42653401 ⁶ , 42778901 ⁷ , 43442701 ¹⁸ , 44397101 ²¹ , 43677001 ²² , 43760301 ²²
860.1380: Storage Stability	N/A	No ⁸	00054672, 42660101 ⁶ , 42958301 ⁹ , 43053601 ¹⁰ , 43989901 ⁸ , 43989901 ¹⁹
860.1500: Magnitude of the Residue in Plants			
<u>Root and Tuber Vegetables Group</u>			
- Potato	50 [180.181]	No ¹¹	00083155, 00114695, 00114718, 00114741, 00114747, 00114750, 00114777, 00114785, 00114795, 42566801 ^{12,13} , 42610301 ⁶ , 42653601 ⁶ , 42653801 ⁶ , 42653901 ⁶
<u>Leafy Vegetables (except Brassica) Group</u>			
- Spinach	0.3 [180.319]	N/A ¹⁴	00114710, 00114715, 00114794
860.1520: Magnitude of the Residue in Processed Food/Feed			
- Potato		No ¹⁵	42566801 ^{13,14} , 42653701 ⁶ , 42660201 ⁶ , 44534501 ¹⁸ , 44736001 ²⁰ , 45426101 ²⁰
860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs			

GLN: Data Requirements	Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Cattle, goats, hogs, horses, and sheep	0.05 [180.319]	No	43884501 ¹⁶
- Milk	0.05 [180.319]	No	00037029, 00054669, 43884501 ¹⁶
860.1400: Magnitude of the Residue in Water, Fish and Irrigated Crops		N/A	00035995, 00035998
860.1850: Rotational Crops (Confined)		N/A ¹⁷	
860.1900: Rotational Crops (Field)		N/A ¹⁷	

1. References were reviewed in the Residue Chemistry Science Chapter of the Reregistration Standard, dated 8/19/87, unless otherwise noted.
2. CBRS Nos. 8942, 9137, 9166, and 9171, DP Barcodes D171613, D172569, D172742, and D172739, 3/10/93, J. Abbotts.
3. Reference 2, Reference 4, and CBRS No. 13232, DP Barcode D199308, 5/18/94, D. Miller.
4. CBRS No. 12452, DP Barcode D194640, 10/8/93, J. Abbotts.
5. The registrant had been requested (DP Barcode D213081, 3/22/95, D. Miller) to submit a revised version of the proposed analytical methods incorporating significant comments made by ACB. The revised method, when received, will be forwarded to FDA for publication in PAM Vol. II.
For the determination of chlorpropham and its 4-HSA metabolite in meat and milk, separate enforcement methods (GC/MSD for chlorpropham and HPLC for 4-HSA) have been submitted by the Task Force (DP Barcode D218755, 9/27/95, D. Miller). Successful ILVs are required before the Agency will initiate method validation.
6. CBRS Nos. 11217, 11422, and 11428, DP Barcodes D186971, D188291, and D188292, 6/21/93, J. Abbotts.
7. CBRS No. 11948, DP Barcode D191727, 7/8/93, J. Abbotts.
8. D222987, 7/9/99, D. Drew.
9. CBRS No. 12695, DP Barcode D195985, 12/9/93, J. Abbotts.
10. DP Barcode D198109, 6/30/94, D. Miller.
11. The submitted data pertaining to magnitude of the residue in potato indicate that the established tolerance may be reduced from 50 ppm to 30 ppm; use must be limited to the following maximum use rates:
 - aerosol fog at 0.022 lb ai/1000 lbs potato in each of two applications 90 days apart followed by direct spray at 0.0104 lb ai/1000 lbs potato; or
 - aerosol fog at 0.033 lbs ai/1000 lbs potato and a second aerosol fog 140 days later at 0.017 lb ai/1000 lbs potato.
12. CBRS No. 11008, DP Barcode D185464, 4/16/93, J. Abbotts.

13. CBRS No. 12273, DP Barcode D193416, 8/11/93, J. Abbotts.
14. There are no registered uses of chlorpropham on spinach. The interim tolerance for spinach should be revoked.
15. CBRS Nos. 11217, 11422, and 11428, DP Barcodes D186971, D188291, and D188292, 6/21/93, J. Abbotts; D210640, 7/9/99, D.Drew. A tolerance of 40 ppm should be established for potato, wet peel.
16. D222987, 7/9/99, D .Drew.
17. The registrants only intend to support postharvest use on stored potatoes. Rotational crop studies are not required to support this use.
18. D210640, 7/9/99, D. Drew.
19. D222987, 7/9/99, D. Drew.
20. D260114, 12/17/01 and D276548, 1/7/02, D. Drew and D281664, 5/6/02, D.Drew (MRIDs 44736001 and 45426101 were determined to be supplemental studies, i.e do not meet all of the 860.1500 Guideline requirements, and were not used for tolerance reassessment;).
21. D283302, 6/2/02, D. Drew (also D185464, 416/93, J. Abbotts; D193416, 8/10/93, J. Abbotts; D240103, 7/1/99, D. Drew)
22. D218755, 9/27/95, D. Miller.